



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/945,655	10/24/97	LOFROTH	J 1103326-283

WHITE & CASE  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2787

HM12/0306

EXAMINER

WEBMAN, E

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/945,655**

Applicant(s)

**Lofroth**

Examiner

**Webman**

Group Art Unit

**1617**



☒ Responsive to communication(s) filed on Nov 22, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-8 and 12-14 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-8 and 12-14 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,5,6,12-14 rejected under 35 U.S.C. 103(a) as being unpatentable over

Rencher.

Rencher teaches a pharmaceutical delivery vehicle comprising xanthan gum (abstract). Water insoluble materials to retard release are specified (column 3, lines 10-14). <sup>Ch</sup> ~~Ch~~olesterol lowering agents are disclosed (column 3, line 43).

Applicants stipulate that fluvastatin is known in the art to reduce cholesterol levels (page 4, lines 19-25).

It would have been obvious to one of ordinary skill to deliver fluvastatin in the vehicle of Rencher in view of the fact that the drug is known in the art to reduce cholesterol.

Applicants argue that the xanthan gum in Rencher is for adhesion, not controlled release, however, no teaching in Rencher is cited. Applicants argue but do not claim release over three hours. <sup>A</sup> Applicants specification merely states "typically" more than three hours.

Claims 1-4, 12-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem et al. or Sakamoto et al.

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Anselem et al. and Sakamoto et al. teach a vehicle comprising a lipid and fat respectively for delivering water-soluble drugs (Abstract). Waxes and paraffin are specified (column 5 lines 31-34 and column 3 line 32 respectively). Applicants stipulate that fluvastatin is water soluble (page 5 line 7).

It would have been obvious to one of ordinary skill to deliver fluvastatin with the vehicle of Anselem et al. or Sakamoto et al. in view of the fact that fluvastatin is water soluble.

Applicants argue that their paraffin, contrary to Anselm et al, is unmixed with other lipids. They argue that, contrary to Sakamoto et al, their paraffin is not melted. However, applicants do not claim unmixed and unmelted paraffin. As to the claimed erosion, the obvious compositions must be erodible because applicants claimed compositions are made from the same ingredients.

Claims 1-2,7-8,12-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Kotwal et al. or Eichel et al.

Kotwal et al. and Eichel et al. teach coated vehicles for controlled release of water soluble drugs (Abstracts). Both disclose ethyl cellulose as a coat for controlled release (column 2 line 40 and Abstract respectively).

Applicants stipulate that fluvastatin is soluble (see above).

Applicants argue that their invention, unlike the prior art, addresses the problem of delivering a highly soluble substance in a sustained release vehicle. However, Rencher delivers boric acid (column 3, line 32), a highly soluble drug, and the remaining references as cited

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above, are all designed for water soluble drugs. With regard to Kotwal et al and Eichel et al, applicants <sup>allude</sup> ~~include~~ to multiple layers and multiple coats respectively, but ~~do~~ neither argue nor claim that their invention precludes such embodiments.

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on M-F from 9AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/sg  
February 26, 2000

A handwritten signature in black ink, appearing to be 'EJ Webman', written above the typed name.

**EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500**